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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	**Lead Case No. 3:21-CV-03825-VC**
THIS DOCUMENT RELATES TO: ALL ACTIONS	**PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR PARTIAL SUMMARY JUDGMENT** The Hon. Vince Chhabria Date: June 8, 2023 Time: 1:00 p.m.

NOTICE OF MOTION AND MOTION FOR PARTIAL SUMMARY JUDGMENT

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, or as soon thereafter as the matter may be heard by the Honorable Vince Chhabria in Courtroom 4, 17th Floor, of the above-entitled Court, located at 450 Golden Gate Avenue, San Francisco, California 94102, Plaintiffs will and hereby do move pursuant to Federal Rule of Civil Procedure 56 for an Order granting Plaintiffs' Motion for Partial Summary Judgment.

This Motion is based on this Notice and Motion, the accompanying Memorandum of Points and Authorities, the Declaration of Jeffrey Corrigan and exhibits thereto, the pleadings and records on file herein, and such other evidence and arguments as may be presented to the Court prior to or at the hearing of this Motion.

STATEMENT OF ISSUES TO BE DECIDED

Whether Plaintiffs are entitled to partial summary judgment because there is no genuine issue of material fact on the following issues related to Plaintiffs' claims:

First, there is no genuine issue of material fact that the da Vinci surgical robot and EndoWrists are separate products.

Second, there is no genuine issue of material fact that there exists a relevant U.S. market for minimally invasive soft tissue surgical robots.

Third, there is no genuine issue of material fact that there exists a relevant U.S. market for EndoWrist repair and replacement.

Fourth, there is no genuine issue of material fact that Intuitive Surgical has monopoly power in the U.S. market for minimally invasive soft tissue surgical robots.

Fifth, there is no genuine issue of material fact that Intuitive Surgical has monopoly power

in the U.S. market for EndoWrist repair and replacement.

Sixth, there is no genuine issue of material fact that FDA's 510(k) clearance requirement does not preclude Plaintiffs from establishing "antitrust injury."

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MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction

Intuitive Surgical, Inc. ("Intuitive") maintains an absolute stranglehold on the market for minimally invasive soft tissue surgical robots ("Robots"), a product that hospitals need to recruit and retain surgeons (without whom hospitals obviously could not function). To access Intuitive's Robot (known as the da Vinci), hospitals must accept Intuitive's conditions that they: (1) not permit third parties to repair their "EndoWrists," the only da Vinci-compatible surgical instruments; (2) discard every EndoWrist that reaches its pre-set "use limit," even if it otherwise remains in working condition; and (3) not permit third parties to service the Robot. These restrictions have prevented hospitals from using independent repair companies ("IRCs") to repair their EndoWrists or service their da Vincis—in contrast to the countless other medical devices for which they use IRCs every day. As a result, Intuitive has been able to force hospitals to replace EndoWrists unnecessarily and to charge monopoly prices for EndoWrists and Robot service and maintenance, artificially inflating the cost to hospitals and patients for da Vinci surgeries. Plaintiffs challenge these unlawful restraints under claims of tying, exclusive dealing, and monopolization in the aftermarkets for EndoWrist repair and replacement and da Vinci servicing.

Plaintiffs seek summary resolution on two sets of issues for which the material facts are not genuinely disputed. First, Plaintiffs' claims require evidence of power in a relevant market, and here the record is clear that (a) Robots and EndoWrists occupy different markets, and (b) Intuitive enjoys monopoly power in both markets. Second, antitrust plaintiffs must establish an "antitrust injury" that "flows from that which makes defendants' acts unlawful." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990). Intuitive disputes Plaintiffs' ability to do so, arguing that FDA regulations, not its own unlawful behavior, block IRCs from repairing

EndoWrists, and from resetting their use counters to keep them in service. But it is undisputed that FDA has not imposed any bar to third-party EndoWrist repair. To the contrary, the agency has declined to impose exactly the requirements Intuitive seeks to blame for Plaintiffs' injuries, even though FDA (a) has been aware of third-party EndoWrist repair and resetting for years, and (b) operates with the understanding that IRCs will provide services in areas where FDA regulations are absent or ambiguous unless and until FDA takes enforcement action to make them stop.

II. Factual Background

There are two general types of surgery: open and minimally invasive. One type of minimally invasive surgery is laparoscopy, in which surgeons make small abdominal incisions and use a thin telescopic rod camera to see inside the body while performing surgery with instruments designed to fit through those incisions. Ex. 1 (Elhauge Rep.) ¶ 14. Minimally invasive robotic surgery ("MIRS") went a step further in the 1990s, with the robot holding the camera and surgical instruments while the surgeon controlled their movements from a console. *Id.* ¶¶ 17–20.[1]

A. The da Vinci achieves market dominance.

In 2000, Intuitive's da Vinci became the first FDA-approved surgical robot in the U.S. *Id.* ¶¶ 23–24. In 2003, Intuitive acquired Computer Motion and phased out its Zeus surgical robot, leaving the da Vinci as the only minimally invasive surgical robot capable of performing soft-tissue surgery (between a patient's pelvis and neck) with a meaningful market share in the U.S.—a distinction it has held ever since. *Id.* ¶ 21. Intuitive has developed and sold multiple generations

[1] *See* Ex. 2 (Curet Dep.) 8:16-22 ("I've seen two revolutions in my surgical lifetime – the laparoscopic revolution and now the robotic revolution."); *see also* Ex. 1 (Elhauge Rep.) ¶¶ 17, 92, 96; Ex. 3 (Elhauge Reply Rep.) ¶ 146. (All exhibits cited in this motion are attached to the Declaration of Jeffrey Corrigan, which is attached hereto.)

of the da Vinci, including the Standard, S, Si, X, Xi, and SP. *Id.* ¶¶ 30–33.

Robots offer capabilities beyond those of laparoscopy. For instance, Robots give surgeons greater dexterity, control, precision, and access, and reduce surgeon fatigue. *Id.* ¶ 20. Further, Robots allow surgeons to perform procedures that are difficult or even impossible to perform using laparoscopy. *Id.* ¶ 93. For these reasons, many surgeons prefer MIRS to open and laparoscopic modalities. Ex. 4 (Francis Dep.) 11:7-17; *see also* Ex. 5 (Intuitive-00128687) at '690.

The Robot market is dominated by the da Vinci. Ex. 1 (Elhauge Rep.) ¶ 112. After the Zeus was discontinued, the U.S. market would not see another Robot until Medrobotics' Flex in 2015. *See id.* n.259. The only other entrant, TransEnterix's Senhance, was approved in 2017. *Id.* n.298. The Flex and Senhance have seen very little commercial success, and Intuitive has retained a market share of over 99% for many years. *Id.* ¶ 112, Table 1; *see also id.* ¶ 113. This is not surprising. Intuitive had an almost two-decade head start on these other Robot manufacturers in a market with high barriers to entry, including intellectual property rights, FDA approval requirements, and high development costs. *See id.* ¶¶ 114-127. Surgeons also view the da Vinci as superior to the Flex and Senhance, and many hospitals report that they cannot attract or retain top surgical talent without having a da Vinci. *See* Ex. 6 (Harrich Dep.) 9:5–9, 12:16–18, 125:13–17, 126:2–7; Ex. 4 (Francis Dep.) 36:6-11; Ex. 7 (Rubach Rep.) ¶¶ 9, 23, 24. In fact, doctors are trained in MIRS predominantly using the da Vinci. *See* Ex. 8 (Intuitive-00011487).

B. Intuitive ties robots to instrument sales.

From the outset, Intuitive always planned to extract monopoly rents from EndoWrists. Indeed, in 1995, Intuitive pitched investors that it intended to [redacted] Ex. 9 (Intuitive-

00595673) at -675. That business model would work, Intuitive explained, [redacted] [redacted] *Id*. at -682 (emphasis added). Intuitive set this course before it [redacted] *Id*. at -691.

Intuitive executed this business model using the da Vinci and its EndoWrist instruments. The da Vinci consists of a patient-side cart, surgeon console, and vision cart. Ex. 1 (Elhauge Rep.) ¶¶ 25, 37. EndoWrists allow for more dexterous surgical motions and additional degrees of freedom relative to traditional laparoscopic instruments. *Id.* ¶ 38. The da Vinci will not recognize any surgical instrument that does not have an Intuitive-generated identification code. As a result, no third-party instruments are compatible with the da Vinci. Ex. 10 (Shaw Dep.) 238:7–15; Ex. 11 (DeSantis Dep.) 25:15-19; 27:5-8. Intuitive also services the robot (but not EndoWrists), including providing preventative maintenance and robot repairs. Ex. 1 (Elhauge Rep.) ¶ 45.

Consistent with this business model, since its inception, Intuitive's contracts with its customers (hospitals and other surgery centers) have prohibited (a) any repair or modification of EndoWrists, and (b) the use of EndoWrists beyond the maximum number of uses mandated by Intuitive. *See* Ex. 12 (Intuitive-00067540) at -540-42; Ex. 13 (Intuitive's Answer) ¶¶ 4, 107. Intuitive set its EndoWrist use limits to achieve its desired margins. *See* Ex. 14 (McGrogan 30(b)(6) Dep.) 35:5–36:23. A 10-second procedure, a 10-hour procedure, or a mistakenly attached instrument not even used during a procedure each counts as one "use." Ex. 7 (Rubach Rep.) ¶¶ 30–32. Intuitive enforces the use limits through the EndoWrists' use-counter memory chip, which renders the instrument useless once the use limit is reached, regardless of the instrument's condition. *See id.* ¶¶ 18, 30; Ex. 1 (Elhauge Rep.) ¶ 42. [redacted] [redacted] Ex. 15 (Vavoso Dep.) 202:24-203:9. To further enforce compliance, [redacted]

[redacted]. Ex. 16 (Jones 30(b)(6) Dep.) 22:15–23:4. [redacted] *See* Ex. 12 (Intuitive-00067540) at -540–42.

If a da Vinci customer violates these provisions, the contract provides that Intuitive may cease servicing the robot, cancel its warranty, terminate the contract, and withhold the sale of instruments and replacement parts. Ex. 13 (Answer) ¶¶ 73, 107; Ex. 1 (Elhauge Rep.) ¶ 254; *see also* Ex. 12 (Intuitive-00067540) at -540–42. [redacted] Ex. 17 (Smith Rep.) ¶ 84(a).

C. Intuitive stifles competition through restrictions on repair and servicing.

Despite the obstacles posed by [redacted] Ex. 18 (REBOTIX174692). In 2016, [redacted] *Id*. at -694. [redacted] Ex. 19 (Intuitive-00047082). In 2018, [redacted] Ex. 18 (REBOTIX174692) at -695.[2] [redacted] Ex. 22 (Intuitive-01020015) at -016. [redacted]

[2] In their separate actions, both Rebotix and Restore survived summary judgment and settled with Intuitive shortly before their respective trial dates. *See* Ex. 20 (Notice of Settlement (Oct. 12, 2022) in *Rebotix*; Ex. 21 (Stip. of Dismissal (Jan. 26, 2023) in *Restore*).

[redacted]. Ex. 23 (Posdal Dep.) 13:19–14:16, 15:14–18:7, Ex. 2; Ex. 24 (Colletti Dep.) 7:24–10:5.

Based on the industry's response to their proposed repair service, [redacted] Ex. 25 (May Dep.) 68:3–9; Ex. 26 (Hamilton Dep.) 58:2–10. Indeed, [redacted] Ex. 27 (Papit Dep.) 86:21–87:9; Ex. 28 (Intuitive-00194074), at -075, -077 [redacted]. [redacted] Ex. 27 (Papit Dep.) 180:24–181:4; Ex. 6 (Harrich Dep.) 38:9–13.

[redacted] *e.g.*, Ex. 29 (Intuitive-00478439), [redacted]. Ex. 16 (Jones Dep.) 36:10–37:7, 80:1–82:16. [redacted] Ex. 30 (Intuitive-00372993).

Intuitive's use limits, however, are set by Intuitive's marketing department, not its engineers, and Intuitive generally has avoided testing instruments to failure or investigating how long they could last (with or without repair). Ex. 14 (McGrogan Dep.) 35:5–36:23, 46:24–47:20; *see also* Ex. 31 (Intuitive-00560955). [redacted] *See* Ex. 32 (Trautman Rep.) ¶ 66 (citing Intuitive-00481167, at -72). [redacted]

[redacted] Ex. 33 (Intuitive-00214241).

Moreover, in spite of Intuitive's claims about the safety of repaired instruments, Intuitive *never* analyzed the IRCs' repair processes nor conducted *any* testing on the repaired instruments,[3] even though it was well aware of Rebotix's representation that [redacted] Ex. 35 (Intuitive-00102938) at -986–87; Ex. 11 (DeSantis Dep.) 244:16–245:11; Ex. 16 (Jones Dep.) 25:6–20, 73:4–22. And when Intuitive's customers questioned Intuitive's safety claims, [redacted].[4] Medical facilities have in fact confirmed that repaired EndoWrists were functionally equivalent to new ones and that, absent Intuitive's restrictions, they would have continued using the instruments. Ex. 6 (Harrich Dep.) 36:17–39:9, 62:6–10, 69:8–16; *see also* Ex. 36 (Madewell Dep.) 47:9–25, 117:5–118:1; Ex. 39 (McDonald Dep.) 17:20–19:20; Ex. 40 (Harvey Dep.) 21:2–14, 58:20–24.

[redacted]. Ex. 30 (Intuitive-00372993) at -

[3] Ex. 34 (Scoville Dep.) 138:8–139:9; *see also* Ex. 16 (Jones Dep.) 25:6–20, 73:4–22 [redacted] Ex. 36 (Madewell Dep.) 104:23-105:18; Ex. 37 (Intuitive-00214562); Ex. 38 (Bair Dep.) 153:19–21. In one such inquiry, a surgery center explained, "[w]e have audited the quality system and testing protocols of our robotics instrument repair partner … and we find no indication that the functionality of the robotic instruments is compromised when re-using the instruments beyond the limited number of times suggested by Intuitive." Ex. 37 (Intuitive-00214562) at -563.

994-95. These were not empty threats. [redacted] Ex. 16 (Jones Dep.) 45:10–14. [redacted] *Id.* 53:5–21; *see also id.* 48:21–51:12, 60:6–22. Intuitive's campaign of threats worked without fail. Ex. 15 (Vavoso Dep.) 226:18–22 [redacted]; *see also* Ex. 53 (May Dep.) 72:9–17 (similar for Restore).

D. Intuitive reacts to competitive entry by Restore and Rebotix.

In 2016—just as Rebotix began offering its services internationally—[redacted] Ex. 41 (Intuitive-00273261); Ex. 35 (Intuitive-00102938). Project Dragon aimed to "displace" and increase barriers to entry for third-party repair companies. Ex. 11 (DeSantis Dep.) 254:19–24; Ex. 34 (Scoville Dep.) 85:10–23. Intuitive concluded "there would be demand for lower-priced, refurbished instruments," Ex. 34 (Scoville Dep.) 33:2–6; that "customers could be satisfied with refurbished devices," *id.* 35:1–35:14; and that EndoWrists' "clinical utility was equivalent or better than new instruments after they have been refurbished." *Id.* 105:1–14. But in 2020, as Restore and Rebotix were being shut out of the market, Intuitive abandoned the project. *Id.*

Intuitive's other effort to [redacted] Ex. 42 (Intuitive-00029174), at -174; Ex. 43 (Intuitive-00583036), at -036–43; Ex. 59 (Intuitive-00471993) at -994. [redacted]

[redacted] Ex. 44, (Intuitive-00552697, at -699); *see also* Ex. 45 (Mario Lowe 30(b)(6) Dep.) 22:6–23. [redacted], Ex. 46 (Peswani Dep.) 108:14–109:10. [redacted] Ex. 14 (McGrogan Dep.) 46:24–47:20; Ex. 31 (Intuitive-00560955), at -995–56. [redacted] Ex. 47 (Intuitive-00556188), at -188–90. [redacted] Ex. 48 (Intuitive-01235518) at -520.

III. Legal Standard

A party may "move for summary judgment" on any "claim or defense—or [any] part of each claim or defense." Fed. R. Civ. P. 56(a). Summary judgment is appropriate if no genuine issue exists regarding any material fact. Fed. R. Civ. P. 56(c). An issue of fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if the resolution of that factual dispute would affect the outcome of the claim or defense. *Miller v. Glenn Miller Prod., Inc.*, 454 F.3d 975, 987 (9th Cir. 2006). The moving party bears the initial burden of showing the absence of an issue of material fact, at which point the nonmoving party must demonstrate a genuine issue of material fact. *Rivera v. Philip Morris, Inc.*, 395 F.3d 1142, 1146 (9th Cir. 2005).

IV. Argument

A. Intuitive has monopoly power in both the Robot and the EndoWrist markets.

To prove that a defendant exercises monopoly power,[5] Plaintiffs must (1) define the relevant product and geographic markets; (2) show that the defendant "owns a dominant share" in those markets; and (3) show that there are "significant barriers to entry" and "existing competitors lack the capacity to increase their output in the short run." *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995). The record leaves no doubt that Intuitive has monopoly power in distinct U.S. markets for (a) Robots and (b) EndoWrists.

1. Da Vincis and EndoWrists are separate products.

Whether da Vincis and EndoWrists are separate products "turns not on the functional relation between them, but rather on the character of the demand for the two items." *Surgical Instrument Serv. Co. v. Intuitive Surgical, Inc.*, 571 F. Supp. 3d 1133, 1139 (N.D. Cal. 2021) ("*SIS*") (quoting *Jefferson Parish Hosp. v. Hyde*, 466 U.S. 2, 19 (1984)). "[S]eparate markets exist in situations where consumers, '*when given a choice*,' opt to purchase the goods from different firms, rather than a single firm." *Id.* (quoting *Rick-Mik*, 532 F.3d at 975) (emphasis added). "The Supreme Court has long recognized that complementary products—however essentially paired—can constitute separate product markets . . . even if demand for one product hinges on demand for another." *Id.* (citing *Kodak*, 504 U.S. at 462–63).

Here, the undisputed evidence proves that, *even under the weight of Intuitive's ban on using*

[5] While Plaintiffs' tying and exclusive dealing claims require at most a showing of market power, *see Rick-Mik Enters., Inc. v. Equilon Enters. LLC*, 532 F.3d 963, 971 (9th Cir. 2008), the record indisputably establishes Intuitive's monopoly power, which "requires, of course, something greater than market power," *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481 (1992).

such services, many "health care providers opted to purchase [EndoWrist] refurbishment services from SIS [and other companies], not from Intuitive Surgical." *SIS*, 571 F. Supp. 3d at 1139; *see* Ex. 28 (Intuitive-00194074), at '075, '077 [redacted]; Ex. 49 (REBOTIX175326); Ex. 50 (Restore-00055937); Ex. 51 (SIS000171). Moreover, these hospitals viewed repaired EndoWrists as functionally equivalent to new EndoWrists from Intuitive. Ex. 6 (Harrich Dep.) 36:17-39:9, 62:6-10, 69:8-16; Ex. 36 (Madewell Dep.) 47:9-25, 117:5-118:1; Ex. 39 (McDonald Dep.) 17:20-19:20; Ex. 40 (Harvey Dep.) 21:2-14, 58:20-24; Ex. 38 (Bair Dep.) 151:13-158:9. [redacted] Ex. 1 (Elhauge Rep.) ¶¶273, 304; Ex. 19 (Intuitive-00047082), at -082; Ex. 52 (Schimmel Dep.) 93:16-95:13; Ex. 23 (Posdal Dep.) 77:14-78:20. These facts offer undisputed proof that there was separate demand for EndoWrist repair and replacement, such that it constitutes a separate product from the da Vinci.[6]

Even apart from the context of IRC repairs, EndoWrists are a separate product from da Vincis. [redacted] Ex. 15 (Vavoso Dep.) 50:20-51:9. Thus, demand for the two products is fundamentally different in quantity and nature, with no fixed ratio between them. Even Intuitive treats the da Vinci robot and EndoWrists as separate products. Its capital sales team sells the robot, while the clinical sales team handles the sales of EndoWrists and accessories. Ex. 54 (Intuitive 10-

[6]Although Intuitive may continue to argue that the "complementary" nature of the da Vinci and EndoWrists makes them part of a single product, this Court already correctly rejected this erroneous legal proposition. *SIS*, 571 F. Supp. 3d at 1139.

K (FY 2020)) at 10; *see also* Ex. 13 (Answer) ¶ 100. In its SEC filings, Intuitive presents its product offerings separately: "systems" include the da Vinci robot while "instruments and accessories" include EndoWrists. Ex. 54 (Intuitive 10-K (FY 2020)) at 6-8. [redacted] Ex. 55 (Smith Dep.) 111:11-112:23. Moreover, instruments for other manufacturers' Robots are offered unbundled, further confirming "it is efficient for a firm to provide" these products separately. *Kodak*, 504 U.S. at 482; Ex. 1 (Elhauge Rep.) ¶¶ 153-54; Ex. 3 (Elhauge Reply) ¶¶ 166-176.

2. Intuitive has monopoly power in the U.S. Robot market.

a. There is a U.S. Robot market.

There is a relevant product market for Robots. A product market includes all products that "have [the] actual or potential ability to deprive each other of significant levels of business," *i.e.*, that are "economic substitutes." *Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc.*, 875 F.2d 1369, 1374 (9th Cir. 1989); *High Tech. Careers v. San Jose Mercury News*, 996 F.2d 987, 990 (9th Cir. 1993). "[A] product market is typically defined to include the pool of goods or services that qualify as economic substitutes because they enjoy reasonable interchangeability of use *and cross-elasticity of demand*." *Thurman*, 875 F.2d at 1374 (emphasis added).

Open and laparoscopic surgical methodologies, the products that Intuitive argue compete most closely with Robots, are not economic substitutes for Robots. The adoption of MIRS [redacted]. *See* Ex. 1 (Elhauge Rep.) fig. 8, ¶ 107. According to Intuitive, [redacted] *See*

Ex. 56 (Intuitive-00269124), at -125. [redacted] *See* Ex. 1 (Elhauge Rep.) ¶¶ 91–94; Ex. 17 (Smith Rep.) ¶ 121; *see also* Ex. 57 (Dickens Dep.) 13:21–233.[7]

There are several reasons this one-way migration has occurred. First, Robots allow surgeons to perform surgeries that are difficult or impossible to perform through laparoscopic or open modalities. *See* Ex. 1 (Elhauge Rep.) ¶ 93; Ex. 57 (Dickens Dep.) 13:9–20; Ex. 61 (Zafar Dep.) 217:25–218:8. Second, many surgeons and patients alike demand Robots. *See* Ex. 62 (Pope Dep.) 27:19–25; Ex. 63 (Donovan Dep) 15:7–16; Ex. 6 (Harrich Dep) 12:16-18, 125:13–17; Ex. 4 (Francis Dep.) 36:6–11; Ex. 64 (Bernier Dep.) 28:3–12; Ex. 58 (Estape Dep.) 65:1–12. Third, offering MIRS confers a unique "halo effect" on hospitals, attracting additional business and revenue for the hospital that laparoscopic and open surgery do not provide. Ex. 7 (Rubach Rep.) ¶ 24; *see also* Ex. 17 (Smith Rep.) ¶ 194.

[redacted].[8] In addition, statements by Intuitive show that, outside of the positions it has adopted for litigation, it has always recognized Robots to be a distinct product market. Ex. 2 (Curet Dep.) 8:16–22 (Intuitive's Chief Medical Officer testified that MIRS is a revolution over laparoscopic surgery); *see also* Ex. 66 (Intuitive-02068246) at -

[7] Hospitals that own a Robot may revert from MIRS to laparoscopic or open surgery *for a particular case*, *e.g.*, because the robot is unavailable. *See* Ex. 58 (Estape Dep.) 20:13-21; Ex. 60 (Burke Dep.) 52:6-19. But this is not a consideration when a hospital is deciding whether to purchase a Robot, which is the relevant decision for purposes of determining market definition. Ex. 1 (Elhauge Rep.) ¶¶ 73, 95; Ex. 3 (Elhauge Reply) ¶¶ 114–17; *see also* Ex. 6 (Harrich Dep.) at 51:7-16.

[8] *See* Ex. 97 (Intuitive-01265649) at -781 [redacted]; Ex. 1 (Elhauge Rep.) ¶¶ 130, 133, 188, 191, 194, 234, 235, 366; Ex. 11 (DeSantis (Rebotix) Dep.) at 249:18-22 (89%).

246–297; Ex. 67 (Intuitive-00269124) at -126; Ex. 68 (Intuitive-00560277) at -381–384. Indeed, as recently as 2020, Intuitive's CFO observed that "***competition isn't yet here***," demonstrating that Intuitive does not view laparoscopic and open surgical tools as being in the same market as Robots. Ex. 70 (Global Healthcare Conference Presentation) at 7.[9] Industry participants and analysts agree. *See* Ex. 61 (Zafar Dep.) 215:20–218:8; Ex. 62 (Pope Dep.) 35:18–36:1; *see generally* Ex. 1 (Elhauge Rep.) ¶ 136 (collecting evidence).

That laparoscopic and (to an even lesser degree) open surgery may to some extent be functional alternatives for some robotic surgery procedures does not put these tools in the same market economically as Robots. As a practical matter, having a da Vinci is seen as critical to attract top surgeons. Ex. 63 (Donovan Dep.) 15:7–10; *see also* Ex. 6 (Harrich Dep.) 11:25–12:10. In fact, surgeons who can perform laparoscopic and robotic surgeries will not work at hospitals that do not offer the latter. Ex. 4 (Francis Dep.) 36:6–11. And, as noted above, many surgeons do not even consider open or laparoscopic surgery to be functional substitutes for certain procedures.

Given these facts, no reasonable jury could find that laparoscopic or open surgery tools are economic substitutes for Robots. Accordingly, Robots are a relevant product market.

The relevant geographical market here (the United States) is undisputed. Indeed, Intuitive has admitted as much in *Restore*, stipulating that "[t]he relevant geographic market for the antitrust claims in this action is the United States." Joint Pretrial Stipulation at 2, 14, *Restore* (Dec. 23, 2022), ECF No. 212; *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 470 n.6 (2013)

[9] *See* Ex. 67 (Intuitive-00269124) at -126 [redacted]; Ex. 11 (DeSantis Dep.) 29:22-30:2 ("Robotics is differentiated from lap and its value proposition. So therefore, when we think about our place in the market, we should be thinking about our robotic offering versus other robotic offerings rather than lap.")

(describing "[f]actual assertions in pleadings and pretrial orders" as "judicial admissions conclusively binding on the party who made them"). At any rate, the undisputed evidence is that Intuitive categorizes the United States as a single market, *see* Ex. 54 (Intuitive 10-K (FY 2020) at 70, 102; *see also* Ex. 1 (Elhauge Rep.) nn.257–258, and Intuitive's expert found [redacted] Ex. 17 (Smith Rep.) n.332.

b. Intuitive has monopoly power in the U.S. Robot market.

"Monopoly power is the 'power to control prices or exclude competition' in the relevant market . . . and exists whenever prices can be raised above the competitive market levels." *High Tech.*, 996 F.2d at 990 (quoting *U.S. v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956); *see also Rebel Oil*, 51 F.3d at 1434 (outlining requirements for demonstrating market power).

[redacted]. *See* Ex. 1 (Elhauge Rep.) ¶¶ 112–13; Ex. 3 (Elhauge Reply) ¶ 5.[10] And, as noted above, [redacted] *See* Ex. 95 (Intuitive-00029346), at -346-47; *see also* Ex. 69 (Intuitive-00366044) at -045; Ex. 11 (DeSantis Dep.) 69:19–24. The industry at large universally agrees. *See* Ex. 62 (Pope Dep.) 31:12–18; Ex. 61 (Zafar Dep.) 16:15-21, 17:23–18:6; *see generally* Ex. 1 (Elhauge Rep.) ¶ 136.

Unsurprisingly, Intuitive faces little pricing constraint from competitors. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) ("If a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly

[10] The installed base of da Vinci robots far exceeds those of Senhance and Flex robots. *See* Ex. 54 Intuitive 10-K (FY 2020) at 10; *see also* Ex. 71 (Vavoso Dep., Ex. 14) [redacted].

power."). [redacted]

[redacted] Ex. 72 (Intuitive-00362751) at -752–753. But competing robots have barely penetrated the U.S. market, allowing Intuitive to continue charging supracompetitive prices. *See supra*, Section IV.A.2.a (noting Intuitive's high profit margins).

[redacted] *See* Ex. 1 (Elhauge Rep.) ¶¶ 114–27; Ex. 17 (Smith Rep.) ¶138, n.363; *see also Rebel Oil*, 51 F.3d at 1434, 1439. These include: the challenge of designing a Robot around existing IP, *see* Ex. 11 (DeSantis Dep.) 12:13–15, 60:4–7; *see also* Ex. 73 (Intuitive-00519980) at -985; the time and investments necessary to obtain FDA clearance of a Robot, *see* Ex. 38 (Bair Dep.) Ex. 4; [redacted], *see* Ex. 73 (Intuitive-00519980) at -985); and [redacted][11] and the costs of switching to another robot type.[12] These barriers keep Intuitive's market dominance unchecked. For example, Johnson & Johnson has spent years and hundreds of millions of dollars developing its "Ottava" robot, but is still over a year away from FDA approval. *See* Ex. 1 (Elhauge Rep.) ¶¶102, 115. [redacted] *See* Ex. 62 (Pope Dep.) 36:13–19.

[11] *E.g.*, Ex. 74 (Intuitive-00278203) at -204 [redacted]

[12] Many surgeons have been trained in MIRS exclusively on da Vinci robots for many years and show a low willingness to switch to new systems. Ex. 11 (DeSantis Dep., Ex. 8) at -204, -222; *see also* Ex. 8 (Intuitive-00011487); Ex. 75 (Intuitive-00121229).

3. Intuitive has monopoly power in the market for EndoWrist repair and replacement.

a. There is a U.S. market for EndoWrist repair and replacement.

There is a single, nationwide market for EndoWrist repair and replacement, as Intuitive has conceded. *See supra*, Section IV.A.2.a. Intuitive, as the only seller of EndoWrists in the U.S., [redacted] *See* Ex. 1 (Elhauge Rep.) ¶ 176. [redacted] *See Id.*; Ex. 76 (Intuitive-00203904-906) at 905; *See* Ex. 1 (Elhauge Rep.) ¶ 164. The FDA regulates the manufacture of EndoWrists at a nationwide level.

There are no economic substitutes for EndoWrists. [redacted] Ex. 15 (Vavoso Dep.) 53:17-55:16. Although traditional laparoscopic and open surgical instruments can be used to perform some (but not all) of the same surgeries as a da Vinci, this does not make them economic substitutes for EndoWrists. Beyond being incompatible with the da Vinci, laparoscopic and open surgical tools are not economic substitutes for the da Vinci and therefore cannot be economic substitutes for EndoWrists needed to perform da Vinci surgeries. (This is even more true once a hospital has purchased or leased a da Vinci for more than a million dollars.) Ex. 1 (Elhauge Rep.) ¶¶ 169-170.

Repaired EndoWrists are practical and economic substitutes for new EndoWrists, and thus are in the same product market as new EndoWrists. Ex. 1 (Elhauge Rep.) ¶ 158; Ex. 39 (McDonald Dep.) 13:20–17:25, 67:22–68:15; Ex. 6 (Harrich Dep.) 38:9–39:3. [redacted]

[redacted] Ex. 1 (Elhauge Rep.) ¶ 296; Ex. 77 (Intuitive-00552993) at 52993; Ex. 34 (Scoville Dep.) 34:4–35:6, 105:1–14. [redacted] Ex. 1 (Elhauge Rep.) ¶¶ 158-161 (noting Intuitive's acknowledgment that each [redacted]; *see also* Ex. 78 (DeSantis Dep., Ex. 11) at -055.

b. Intuitive has monopoly power in the EndoWrist market.

Intuitive's market share in the EndoWrist repair and replacement market has been at least 99.87% throughout the Class Period, with IRC-repaired EndoWrists making up the remainder. *See* Ex. 1 (Elhauge Rep.) ¶ 179 n.436 & Table 2 (calculating market share). [redacted] *See id.* ¶ 242; Ex. 36 (Madewell Dep.) 119:8–18. In using IRC-repaired EndoWrists, Intuitive's customers risk Intuitive discontinuing their robot service, warranty, and future supply of instruments. Ex. 1 (Elhauge Rep.) ¶ 242; *see also* Ex. 13 (Answer) ¶¶ 82, 107. This prohibition is a standard contract provision, binding every Intuitive customer throughout the United States over the Class Period. Ex. 38 (Bair Dep.) 99:24-100:8; Ex. 17 (Smith Rep.) ¶ 84(a).

Intuitive's monopoly power is protected by high entry barriers. Ex. 1 (Elhauge Rep.) ¶¶ 180–85. Intuitive's prohibitions on third-party EndoWrist repair lock out competitors. Ex. 79 (Parker Dep.) 130:6–23, 139:23–140:8. [redacted]

[redacted] Ex. 80 (REBOTIX110980) at -981; Ex. 1 Elhauge Rep.) ¶¶ 262, 275; Ex. 26 (Hamilton Dep.) 42:1–11; Ex. 54 (Intuitive 10K FY2020) at 12.

B. There is no regulatory bar to showing antitrust injury.

To prevail on their EndoWrist-related claims, Plaintiffs must establish "antitrust injury," *Atl. Richfield*, 495 U.S. at 334, meaning Plaintiffs must "show that diminished consumer choices and increased prices are the result of a less competitive market due to either artificial restraints or predatory and exclusionary conduct." *FTC v. Qualcomm, Inc.*, 969 F.3d 974, 990 (9th Cir. 2020).

Intuitive has maintained that Plaintiffs are "unable to establish antitrust injury" because FDA supposedly "has required 510(k) clearance for [] EndoWrist 'repair' service," rendering such service "unlawful" absent 510(k) clearance. Ex. 81 (Mot. to Stay), at 7–8; Ex. 82 (Interrog. Resps.), at 16–17. In Intuitive's telling, the fact that (at least until recently) no third-party EndoWrist repair company had secured 510(k) clearance created an insurmountable bar to establishing antitrust injury.[13] But there are no material facts to support Intuitive's effort to position 510(k) clearance as a silver-bullet defense. Thus, Plaintiffs seek summary judgment that IRCs would not have been blocked by FDA from competing in the EndoWrist repair and replacement market.

1. Rebotix and Restore repaired EndoWrists without 510(k) clearance.

For Intuitive to succeed with its "regulatory bar" argument, it must show that FDA would

[13] Although this argument is predicated on the position that no EndoWrist repair company had (or, in the but-for world, could have) received 510(k) clearance, on September 30, 2022, a Restore affiliate, Iconocare, received 510(k) clearance from FDA to market a refurbished EndoWrist. *See* Ex. 83 (Claiborne Dep.) Ex. 301. [redacted] *See* Ex. 1 (Elhauge Rep.) ¶¶ 285-89; Ex. 3 (Elhauge Reply) ¶ 297(f)-(g).

have blocked IRCs from their EndoWrist repair activities absent 510(k) clearance (and that IRCs would not have obtained such clearance in the but-for world). Record evidence, however, unequivocally shows both that FDA has not determined that IRCs need 510(k) clearance to repair EndoWrists and that FDA has no inclination to bring enforcement actions to enjoin them from doing so. In the absence of any definite stance to the contrary, IRCs "could and would continue to service, refurbish, reprocess and reset EndoWrists and simply work with FDA to satisfy any concerns it may raise." Ex. 84 (Trautman Reply) ¶ 80; *see also* Ex. 32 (Trautman Rep.) ¶¶ 59-61.

[redacted] *See* Ex. 22 (Intuitive-01020015) at -016; Ex. 65 (Gibson Dep.) 132:17-24. [redacted] Ex. 53 (May Dep.) 77:17-78:4; Ex. 18 (REBOTIX174692) at -695; Ex. 30 (Intuitive-00372993) at -993–94. [redacted][14] For example, an FDA reviewer informed Rebotix that "the [a]gency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and [510(k)] clearance." Ex. 85 (REBOTIX-175839) at -840. But when Rebotix sought to appeal that "belief," the same reviewer explained that the agency had conducted only "a preliminary **informal assessment** of the limited materials

14 [redacted] Ex. 77 (Intuitive-00552993) at -993. [redacted] Ex. 78 (Intuitive-00566055) at -055.

previously provided by Rebotix," and that "FDA has *not conducted an official regulatory evaluation*." *Id.* at -839 (second emphasis added). Because "[i]nformal communications with FDA staff do not represent the formal position of FDA and do not bind or otherwise obligate or commit the agency to the views expressed," the reviewer explained that "there [wa]s nothing for Rebotix to appeal at th[at] time." *Id.* And if informal communications do not bind the agency, they surely do not bind IRCs either.[15]

That Rebotix continued to press the issue, even after FDA contacted the company with concerns about its lack of 510(k) clearance, is unsurprising. It is common practice to continue marketing a medical device unless and until FDA affirmatively, officially, and unambiguously establishes that the device is subject to some regulatory requirement. Even where FDA explicitly "request[s] [that] a company stop engaging in [some] activity," "many, many, many times th[ose] activities would absolutely not be stopped" while that company engages FDA on the issue. Ex. 86 (Trautman Dep.) 255:19-256:3.[16]

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[15] That Iconocare successfully sought 510(k) clearance does not indicate that FDA has ever required 510(k) clearance for EndoWrist repairs. *See* Ex. 83 (Claiborne Dep.) Ex. 301. [redacted] Ex. 84 (Trautman Reply) ¶ 30. As a result, "[w]hen Iconocare decided to seek 510(k) clearance for its own business purposes," such as countering Intuitive's campaign to scare hospitals with false claims that FDA requires EndoWrist servicers to have 510(k) clearance, "the agency simply accepted Iconocare's position and reviewed it as it would any other 510(k) application." *Id.* ¶ 34. FDA did not need to determine whether Iconocare actually is a "remanufacturer" for 510(k) purposes, because the fact of Iconocare's application allowed the agency simply to assume as much in granting clearance.

[16] To take an example highlighted by Intuitive's FDA expert and far more extreme than the EndoWrists at issue here, [redacted] (Foreman Rep.) ¶ 6. [redacted], Ex. 87 (Foreman Dep.) 17:11–18:14; *see also id.* 18:18–19:15 [redacted].

2. FDA has not required 510(k) clearance for EndoWrist repair.

FDA's refusal to require 510(k) clearance for EndoWrist repair is consistent with its approach to medical device repair more generally. In discharging its duty to ensure the safety of medical devices in the U.S., *see Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000), FDA's goal is to "advance[e] the public health by helping to speed innovations that make medical products more effective, safer, and more affordable," Ex. 88 (Foreman Rep.) ¶ 18 n.1. To that end, FDA imposes "special controls" for medical devices only when necessary to ensure the device's "safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B). One such control is 510(k) clearance. *See* 21 U.S.C. § 360(k).

21 C.F.R. § 807.81(a) governs the scope of 510(k) clearance, and provides that "each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission" prior to the "introduction into interstate commerce for commercial distribution of a device intended for human use" if that device meets one of three criteria. 21 C.F.R. § 807.81(a). As relevant here, the third of those criteria is met where the device "is about to [undergo] . . . [a] change or modification … that could significantly affect the safety or effectiveness of the device . . . [or] [a] major change or modification in the intended use of the device." *Id.*; *see also* Ex. 32 (Trautman Report) ¶ 29; *accord* Ex. 87 (Foreman Dep.) 66:8–22.

Therefore, in the context of medical device repair or refurbishment, two conditions must be met for 510(k) clearance to be required. First, the entity must be a "remanufacturer," defined as "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety

specifications, or intended use." 21 C.F.R. § 820.3(w).[17] Second, the "remanufacturer" must intend to "introduce[e] [that device] into interstate commerce for commercial distribution," 21 C.F.R. § 807.81(a), where "commercial distribution means any distribution of a device intended for human use which is *held or offered for sale*," 21 C.F.R. § 807.3(b) (emphasis added).

FDA has acknowledged substantial ambiguity in the application of these standards. Indeed, as far back as 1998, FDA revoked guidance that required "reconditioners" and "rebuilders" to seek 510(k) clearance, and issued an advance notice of proposed rulemaking "to consider identifying the used device market, for regulatory purposes, in terms of 'refurbishers,' 'as-is remarketers,' and 'servicers' whose activities do not significantly change the safety, performance, or use of a device." 63 Fed. Reg. 67076-01 (Dec. 4, 1998). FDA, however, has never issued this proposed rulemaking. Ex. 84 (Trautman Reply) ¶¶ 7, 15. As recently as 2018, FDA acknowledged the blurred "distinction between servicing," which does not meet the first requirement for 510(k) clearance, "and remanufacturing," which does. Ex. 89 (2018 FDA White Paper) at 1–2; *see also* Ex. 84 (Trautman Reply) ¶¶ 20, 53. And even though FDA's proposed guidance meant to "help[] entities distinguish servicing from remanufacturing," Ex. 89 (2018 FDA White Paper) at 5, industry observers complained that this guidance "leaves too much room for interpretation," Ex. 84 (Trautman Reply) ¶ 20. To date, FDA has not finalized any such guidance. *See id.* ¶¶ 7, 15.

There is good reason for FDA's caution in this area. FDA "understands" that requiring

[17] This is because 21 C.F.R. § 807.20 provides that entities "engage in the *manufacture*, preparation, propagation, compounding, assembly, or processing of a device intended for human use *shall register*," 21 C.F.R. § 807.20(a) (emphases added), and "[m]anufacturer" is defined elsewhere to "include[] . . . remanufacturing," 21 C.F.R. § 820.3(o); *see also* Ex. 84 (Trautman Reply) ¶ 53 (explaining that "[m]anufacturers and remanufacturers are subject to FDA requirements, such as . . . premarket notification," whereas "legal entities that do not fall into those definitions, such as providers of servicing, refurbishing, or reprocessing . . . are not.").

third-party medical device repair companies "to register as . . . remanufacturers and abide by relevant regulations would substantially increase the costs to hospitals (and, ultimately, to patients)," and the agency "does not see the public health case" to justify such a cost. *Id.* ¶ 53.[18]

3. Intuitive's conduct confirms that 510(k) clearance is not an entry bar.

Between 2013 and 2020, Intuitive itself repeatedly increased the use limits of its EndoWrists without seeking 510(k) clearance—a fact that further undermines its litigation position that increasing EndoWrist use limits unambiguously requires 510(k) clearance. In 2013, Intuitive submitted testing supporting 5 uses for its Xi EndoWrists in its 510(k) application, then marketed those same instruments with 10 uses without seeking additional clearance.[19] [redacted] *See* Ex. 90 (Intuitive-00552716) at -718; Ex. 44 (Intuitive-00552697) at -700; Ex. 96 (Intuitive-00552728) at -729. [redacted] *See* Ex. 91 (Intuitive-00423534) at -573–574 [redacted] It was not until some six months into this litigation that Intuitive repositioned its Extended Use Program by seeking 510(k) clearance to increase EndoWrist use limits, after nearly a decade of marketing those EndoWrists with use limits far beyond those

[18] *See also* Ex. 86 (Trautman Dep.) 275:16-20 ("[T]hey [FDA] very overtly said, we do not find compelling evidence that says that there is any public health harm in the activities [and] therefore has made the decision that right now the economic burden of mak[ing]" those activities subject to heightened regulatory requirements was unjustifiable).

[19] *See* Ex. 45 (Lowe 30(b)(6) Dep.) at 30:4–9; *see also* Ex. 92 (Perry Dep.) 108:24–25 [redacted]; Ex. 93 (Intuitive-02038766) at -766 (Perry Dep. Ex. 82) [redacted]

identified in their original applications. [redacted] *See* Ex. 94 (Claiborne Dep.) 33:25–35:23.

[redacted] *See* Ex. 45 (Lowe 30(b)(6) Dep.) at 35; Ex. 94 (Claiborne Dep.) 29–30, 36–41. Despite Intuitive's effort to retroactively argue that 510(k) clearance is and always has been required to extend the uses on EndoWrists, its own actions reveal its understanding that such clearance has never been necessary unless and until FDA actually requires it with the force of law.

Intuitive's own conduct, in other words, belies its contention that EndoWrist repair unambiguously is subject to the 510(k) clearance requirement. The illusory (or, at most, ambiguous) nature of such a requirement, in turn, means it could not and would not bar competitive entry—or Plaintiffs' ability to demonstrate antitrust injury flowing from Intuitive's unlawful behavior. *Cf. Qualcomm*, 969 F.3d at 990. Because there is no "FDA rule, policy, or guidance document outlining a new policy to the contrary," third parties interested in repairing EndoWrists "could and would . . . service or refurbish EndoWrists for hospital clients" without 510(k) clearance. Ex. 84 (Trautman Reply) ¶ 82.

V. Conclusion

For the foregoing reasons, Plaintiffs are entitled to partial summary judgment on the following issues: (1) Intuitive has monopoly power in the Robot and EndoWrist repair and replacement markets; and (2) IRCs would not have been blocked by FDA from competing in the EndoWrist repair and replacement market in the but-for world.

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Respectfully submitted,

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